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10/826,473	04/16/2004	Barry M. Tydings	56990-010601	1502
33717 7590 12/22/2008 GREENBERG TRAUIG LLP (L.A.) 2450 COLORADO AVENUE, SUITE 400E INTELLECTUAL PROPERTY DEPARTMENT SANTA MONICA, CA 90404				
EXAMINER SIEFKE, SAMUEL P				
ART UNIT		PAPER NUMBER		
1797				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/826,473

**Applicant(s)**

TYDINGS ET AL.

**Examiner**

SAM P. SIEFKE

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION3

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 67 recites, "the urine wicks up the wick portion until it reaches an overlapped portion of the wicking portion **and** the first portion of the assay strip and thereafter flows upwards in the first portion of the assay strip." The instant specification gives two embodiments of what the overlapped material can be. From the instant specification page 5, line 1, "The top portion of the reagent strip 12 is bent over the top edge 15 of the backing 8 and overlapped on the wicking paper 10.

The second option for the overlapped material is from page 5, lines 2-3, "Alternatively, the wicking material 10 can be folded over the top edge 15 and overlapped onto the assay strips 12." Therefore, the limitation "overlapped portion of the wicking portion and the first portion of the assay strip can not be overlapped together because it is either the wicking portion that is overlapped or the assay strip portion that is overlapped.

In line 23 of claim 67, the Applicant then recites the urine thereafter flows in the first overlapped portion of the assay strip. One cannot say the wicking material is overlapped then go ahead and say the assay strip is overlapped.

In claim 68, the claimed limitations will only further limit claim 67 when the embodiment which comprises the top portion of the reagent strip 12 is bent over the top edge 15 of the backing 8 and overlapped on the wicking paper 10. This is not the case because claim 67 provides the wicking material being bent over the backing.

Claim 69 includes the limitation wicking portion and first portion of the assay strip. This is new matter because only one of the wicking or the assay strip can be bent over top edge 15 and overlapped on the wicking paper 10.

Claim 70, the Examiner can not locate where in the specification or the drawings that indicates the wicking is located in an elevated position above the base.

Claim 71 and 72, see above comment with respect to the wicking. Further the specification is silent on elevating the assay portion.

Claim 73-75 recite a second portion of the assay strip joined to the first portion of the assay strip. The Examiner does not see where in the specification this is recited. The specification recites at least one assay strip but does state that it comprises different portions nor talk about how they are joined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 67-75 are rejected under 35 U.S.C. 102(b) as being anticipated by  
MacKay et al. (USPN 5,656,502).

MacKay discloses a test strip holder that is placed into a container that holds a sample to be tested. A test strip is disposed in a holder having a backing having a front surface (fig. 5, ref. 26) and is in liquid transmittable contact with a wicking (35, col. 7, lines 19-24), the wicking has a lower portion proximal to the base of the container (Fig. 3a), the urine wicks solely up the wick until it reaches the assay strip, the container is in an upright position (fig 3a), a front cover (fig. 4 ref. 22) provided on the front surface of the backing for locating the assay strip to the backing, the backing together with the front cover and the assay strip being located adjacent a wall of the container and extending from a position proximal to the top of the container to a position proximal to the bottom of the container so that in use the action of the urine consists of wicking solely upwardly along the wicking in the container from the base toward the top.

Claims 67-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Klimov et al. (USPN 5,770,458).

Klimov discloses an assaying device and method for in field analysis of a specimen. The assembly comprises: a partially transparent container (1a) having a opening for collecting a urine sample (fig. 1a, 1b); a wall (110, liquid impermeable); a cover for sealing the container (col. 10, lines 47-51); an assay assembly having at least one assay strip (101) being in liquid transmittable contact with a wicking material (109), the wicking material being in communication with the urine (when the urine is filled to over flow into the collection portion in fig. 1b, the upper top above wicking 109); the assay strip being directed adjacent to the wall of the container thereby being readable through the container wall (fig. 1, cover 48 is transparent ,col. 10, lines 53-57); the assay strips are separated by longitudinal slots; (fig. 1a); a transverse slot for accommodating the end of the test strips (fig. 1a bottom of test strips); a series of assay strips in parallel relationship (fig. 1a); assay strip is substantially the same height of the container (fig. 1a); the assay assembly conforms to the inner wall of the container (fig. 1a.); a screw on cap (not shown but has option for screw on cap and is disclosed fig. 1a col. 10, lines 47-51).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 21-30 of U.S. Patent No. 6,805,837. The presently pending claims 58-66 are a broader version of Patent No. 6,805,837. 6,805,837 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,805,837.

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,379,620. The presently pending claims 58-66 are a broader version of Patent No. 6,379,620. 6,379,620 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,379,620.

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,805,838. The presently pending claims 58-66 are a broader version of Patent No. 6,805,838.

6,805,838 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,805,838.

Claims 67-75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,730,268. The presently pending claims 58-66 are a broader version of Patent No. 6,730,268. 6,730,268 claims include all the limitations found in the presently pending claims. Thus, the presently pending claims cover all the subject matter of 6,730,268.

### ***Response to Arguments***

Applicant's arguments filed 12/12/08 have been fully considered but they are not persuasive. There are still significant problems with the claimed limitations of the instant application. Applicant has tried numerous times to manipulate the embodiments of the claimed invention to overcome prior art but still new matter rejections arise because the specification only shows two embodiments.

The arguments presented with respect to the rejections under Obvious type Double patenting are not persuasive.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/  
Primary Examiner, Art Unit 1797